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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,779	07/03/2000	MARKUS POMPEJUS	48715	2744

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KEIL & WEINKAUF
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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/26/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,779

Applicant(s)

POMPEJUS ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 24 January 2002 (Certificate of Mailing date 29 November 2001) and 4 March 2002 have been entered. In the earlier amendment, claims 1, 2 and 10 were amended. In the most recent amendment, claims 1-4 were amended and new claims 16 and 17 were presented.

It is noted that in the amendment filed 24 January 2002, the clean version of claim 10 did not reflect the deletion indicated in the marked up version of claim 10. In such situations, the clean version of the claim is the accepted version of the claim. Applicant is, however, urged to review the marked up and clean versions of claim 10 to make sure the desired claim language is pending.

Claims 1-17 are pending.

Corrected Filing Receipt

1. Applicant has twice requested a corrected filing receipt, filed 26 March 2001 and 29 August 2001. In both requests, Applicant asserts that the error is the Patent Office's and that therefore no fee is due. This assertion is incorrect. Attached is a copy of the first page of the transmittal letter submitted by Applicant which accompanied the filing of

the application. As indicated in yellow highlighting, the International Filing Date of PCT/EP98/08382 is listed as 15 January 1998. Thus, the error on the Filing Receipt is due to Applicant's error on the transmittal letter and it has not been corrected as no fee was filed.

Specification

2. The abstract of the disclosure is objected to because it has two paragraphs.

Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: On p. 3, lines 30-31 is the following sentence: "The amino-acid sequence derived from SEQ ID NO: 1 is to be seen in SEQ ID NO: 1". This statement makes no sense as SEQ ID NO: 1 refers to a nucleotide sequence.

Appropriate correction is required.

Claim Objections

4. Claim 12 is objected to because of the following informalities: Claim 12 would be grammatically improved if a "the" were inserted in front of the word "microorganism" on line 2. Appropriate correction is required.

Response to Amendment

5. The rejection of claims 1-4 under 35 USC §101 as being directed to non-statutory subject matter has been withdrawn in view of Applicant's amendments.

The rejection of claim 2 under 35 USC §112, 2nd paragraph, as being indefinite is withdrawn in view of Applicant's amendments

6. Claims 1-15, and new claims 16 and 17, stand rejected under 25 USC §112, 1st paragraph for lack of written description for reasons of record and as further discussed below.

7. New grounds of rejection are presented below.

Response to Arguments

8. With respect to the rejection of claims 1-15, and new claims 16 and 17, under 35 USC §112, 1st paragraph for lack of written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that one of ordinary skill in the art should be able to isolate functionally active 80% homologs because of the teachings in the specification, including p. 3, lines 26-44, p. 4, lines 1-7 and Example 9 which describes the construction of an *A. gossypii* ura3- mutant. These arguments are not persuasive for several reasons.

First, being able to isolate or not isolate the claimed homologs is relevant to an enablement rejection, however it is not germane to the rejection at hand, based on lack of written description.

Second, as described in MPEP 2361IA, "a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence". Thus, while the specification may teach a mutant that may be used in an assay for isolating only functionally active homologs, this does not suffice for written description purposes.

Third, the specification defines a homolog as encompassing allelic variants which may comprise "functional variants which are obtainable by deletion, insertion or substitution of nucleotides" (p. 3, lines 32-34) and encompassing promoter variants (p. 4, lines 9-10). The specification however is entirely silent on critical structure-function teachings. For instance, the specification does not teach where such deletions, insertions or substitutions may be made in the sequence and have the polypeptide retain function. Indeed, the specification is entirely silent on where such deletions, insertions or substitutions may be made to inactivate enzymatic function such that the modified SEQ ID No. 1 sequence encodes an ura3- mutant for use in generating organisms which are uracil-auxotrophs. There are no teachings at all of what sequences are part of: 1) the active site of the enzyme, 2) the binding pocket of the enzyme or 3) the hydrophobic core which is essential to the proper folding and three-

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dimensional structure of the enzyme. Absent these critical structure-function teachings, it is clear that Applicant did not have possession of homologs which have 80% homology to SEQ ID No. 1, whether these homologs are functional or not. The specification teaches a single species, SEQ ID NO. 1 which encodes a functional orotidine-5'-phosphate decarboxylase. This single species is not representative of the broad genus encompassed by the claims. The rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting "isolated from microorganisms". Is the claim intended to recite a single gene being isolated from a plurality of microorganisms?

Claim 9 recites the limitation "the organisms" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is vague and indefinite in lacking a step that clearly relates back to the preamble. Amending the claim to recite "thereby producing uracil-auxotrophic microorganisms" would overcome this rejection.

Claim 10 is vague and indefinite in its recitation on lines 4-8 which start with the phrase "as claimed in claim 1 together with as least one other nucleic acid sequence...." and ends with "...as claimed in claim 1 together with at least one other nucleic acid sequence". It is unclear what the claim encompasses as a result of the apparent redundancy.

Claim 14 is vague and indefinite in lacking a step that clearly relates back to the preamble. The method step recited is "transforming cells" however the method preamble states "A process for selecting cells".

Claim 15 is vague and indefinite in reciting "the process as claimed in claim 14 for *Ashbya gossypii*". Does this mean that the cells transformed and selected in the process of claim 14 are *Ashbya gossypii*? This rejection would be overcome by amending claim 15 to recite "The process according to claim 14 wherein said cells are *Ashbya gossypii*".

Claims 16 and 17 are vague and indefinite as each is drawn to "homologs". Are these claims drawn to a composition comprised of homologs or are the claims drawn to a single homolog?

Conclusion

Claims 1-17 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a

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paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

August 26, 2002



REMY YUCEL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Attachment(s) 6). Other: Copy of Papers Originally Filed information.

09/582779

TRANSMITTAL LETTER TO THE UNITED STATES

ATTORNEY'S DOCKET NUMBER 48715

DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.
PCT/EP 98/08382INTERNATIONAL FILING DATE
15 January 1998PRIORITY DATE CLAIMED
15 January 1998

TITLE OF INVENTION: OROTIDINE-5'-PHOSPHATE DECARBOXYLASE GENE, GENE CONSTRUCT COMPRISING THIS GENE AND ITS USE

APPLICANT(S) FOR DO/EO/US Markus POMPEJUS, Jose Luis Revuelta DOVAL, Maria Angeles Santos GARCIA

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. /X/ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
 2. / / This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
 3. /X/ This express request to begin national examination procedures (35 U.S.C.371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
 4. /x / A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
 5. /X/ A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a./X/ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b./ / has been transmitted by the International Bureau.
 - c./ / is not required, as the application was filed in the United States Receiving Office (RO/USO).
 6. /X/ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
 7. /X/ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a./X/ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b./ / have been transmitted by the International Bureau.
 - c./ / have not been made; however, the time limit for making such amendments has NOT expired.
 - d./ / have not been made and will not be made.
 8. /X/ A translation of the amendments to the claims under PCT Article 19(35 U.S.C. 371(c)(3)).
 9. /X/ An oath or declaration of the inventor(s)(35 U.S.C. 371(c)(4)).
 10. / / A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11. to 16. below concern other document(s) or information included:
- 11./X/ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 - 12./X/ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
 - 13./X/ A FIRST preliminary amendment.
/ / A SECOND or SUBSEQUENT preliminary amendment.
 14. / / A substitute specification.
 15. / / A change of power of attorney and/or address letter.
 - 16./x / Other items or information.
International Search Report
International Preliminary Examination Report

Paper No. 20 Attach.

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The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

4 March 2002

25 Feb. 2002

Papers 17+18

8 Feb. 2002

29 Nov. 2001

Paper 13 duplicate (true
mailed copy)

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

Part of Paper No. 20